IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CATALYST PHARMACEUTICALS, INC. and SERB SA, *Plaintiffs,* v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., *Defendants.*	C.A. No. 2:23-cv-01197-MCA-JRA

JOINT PROPOSED DISCOVERY PLAN

Pursuant to Fed. R. Civ. P. 16 and 26 and L. Civ. R. 16.1 and 26.1, and the Court's April 21, 2023 Letter Order (ECF No. 32) and May 1, 2023 Text Order (ECF No. 37), Plaintiffs Catalyst Pharmaceuticals, Inc. ("Catalyst") and SERB SA ("SERB") (collectively, "Plaintiffs") and Defendants Lupin Ltd. ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin" or "Defendants") met and conferred via email between May 2, 2023 and May 4, 2023, pursuant to Fed. R. Civ. P. 26(f) and hereby submit the following proposed Joint Discovery Plan in advance of the May 8, 2023 Initial Scheduling Conference.

1. The name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.

For Plaintiffs Catalyst Pharmaceuticals, Inc. and SERB SA:	*For Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc.:*
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2. A brief description of the case, including the causes of action and defenses asserted.

Plaintiffs brought this patent infringement action under, *inter alia*, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2) in response to Lupin filing of Abbreviated New Drug Application ("ANDA") No. 217996 ("the Lupin ANDA") with the United States Food and Drug Administration ("FDA") for approval to market a generic Amifampridine Tablets, 10 mg product and Lupin's notice of same.

Lupin's notice, dated January 26, 2023 and received by Catalyst on January 27, 2023, stated that ANDA No. 217996 identifies Catalyst's Firdapse® (amifampridine) Tablets, 10 mg drug product (NDA No. 208078) as the Reference Listed Drug. Lupin's notice further stated that ANDA No. 217996 included a "Paragraph IV certification" alleging that U.S. Patent Nos. 10,626,088; 10,793,893; 11,060,128; 11,268,128; 11,274,331; and 11,274,332 ("the patents-in-suit")—each listed in the Orange Book in connection with Catalyst's Firdapse® product—are invalid or would not be infringed by Lupin's proposed generic product described in the Lupin ANDA.

Lupin filed its Answer, Affirmative Defenses, and Counterclaims on May 3, 2023. Lupin produced the Lupin ANDA under the local patent rule on the same day.

3. Have settlement discussions taken place? No

4. The parties have met pursuant to Fed. R. Civ. P. 26(f).

5. The parties have not exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefor.

The parties intend to exchange Rule 26(a)(1) disclosures within the timeframe set forth in the parties' proposed schedule attached hereto as Exhibit A.

6. Explain any problems in connection with completing the disclosures required by Fed R. Civ. P. 26(a)(1).

The parties do not anticipate having any problems completing the Rule 26(a)(1) disclosures. The parties will exchange the Rule 26(a)(1) disclosures within the timeframe set forth in the parties' proposed schedule attached hereto as Exhibit A.

7. The parties [have / have not] filed disclosures of third-party litigation funding. See Local Civil Rule 7.1.1.

The parties will comply with the requirements of Local Civil Rule 7.1.1.

8. The parties have not conducted discovery other than the above disclosures and Lupin's production of the Lupin ANDA.

9. Proposed joint discovery plan:

(a) Discovery is needed on the following subjects:

1. Plaintiffs' allegations of infringement and validity of the patents-in-suit;

2. Lupin's allegations of noninfringement and invalidity of the patents-in-suit;

3. Plaintiffs' request for injunctive relief;

4. Whether this case is exceptional under 35 U.S.C. § 285;

5. The Lupin ANDA and FDA correspondence related thereto, including all amendments, supplemental filings, deficiencies, and deficiency responses;

6. All discovery required by this District's Local Patent Rules, including L. Pat. R. 3.6(j)(2);

7. Research and development regarding or relating to the product described in the Lupin ANDA;

8. Lupin's paragraph IV certification, notice letter, and Lupin's decision to file the Lupin ANDA;

9. Samples of the product described in the Lupin ANDA;

10. Plaintiffs' NDA No. 208078 and the research and development relating to the products disclosed therein, and FDA correspondence related to said NDA;

11. Sales and marketing information relating to the products described in Plaintiffs' NDA No. 208078;

12. Prosecution of the patents-in-suit and related patents and/or applications;

13. Prior art and other knowledge relating to the subject matters of the patents-in-suit;

14. Lupin's forecasted sales and marketing information relating to the products described in the Lupin ANDA; and

15. Any additional discovery that may be required and/or identified during the course of this litigation.

(b) Discovery should not be conducted in phases or be limited to particular issues.

(c) Proposed schedule:

The parties' proposed schedule is attached hereto as Exhibit A.

(d) No special discovery mechanism or procedure is requested at this time.

(e) A pretrial conference may take place on:

The parties' proposed schedule is attached hereto as Exhibit A.

(f) Trial date: The parties' proposed schedule is attached hereto as Exhibit A.

(g) Non-Jury Trial

10. Do you anticipate any special discovery needs (i.e. videotape/telephone depositions, problems with out-of-state witnesses or documents, etc)?

The parties anticipate utilizing videotaped depositions. The parties will confer on the most efficient way to proceed with depositions (remote or in person), including in view of travel restrictions, public health guidelines, and other factors relating to the COVID-19 pandemic. The parties will work together to schedule depositions and make efforts to make all witnesses available in the United States or, if the parties agree to present witnesses remotely, in a jurisdiction in which U.S. discovery is permissible and lawful.

11. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced?

No.

12. Do you anticipate entry of a Discovery Confidentiality Order? *See* L. Civ. R. 5.3(b) and Appendix S.

Yes the parties will submit a proposed Discovery Confidentiality Order pursuant to L. Pat. R. 2.2 according to the schedule set by the Court.

13. Do you anticipate any discovery problem(s) not listed above? Describe.

No.

14. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.)

Voluntary arbitration, mediation, appointment of a special master, and other special procedures are not necessary or appropriate at this time. The parties propose that they meet and confer following the close of expert discovery, or at another time set by the Court, to reassess this issue and provide a joint report to the Court.

15. Is this case appropriate for bifurcation?

No.

16. An interim status/settlement conference (with clients in attendance) should be held in January 2024.

17. We do not consent to the trial being conducted by a Magistrate Judge.

18. Identify any other issues to address at the Rule 16 Scheduling Conference.

N/A.

Dated: May 4, 2023

Respectfully Submitted by:

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